DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 01D–0294 and 01D–0295]

Draft Guidances for Industry on Providing Regulatory Submissions to Office of Food Additive Safety in Electronic Format: General Considerations and for Food Additive and Color Additive Petitions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of two draft guidances for industry entitled "Providing Regulatory Submissions to Office of Food Additive Safety in Electronic Format—General Considerations" and "Providing Regulatory Submissions to Office of Food Additive Safety in Electronic Format for Food Additive and Color Additive Petitions." These documents are the first in a series of guidance documents intended to provide guidance for industry regarding the preparation of regulatory submissions in electronic format to the Office of Food Additive Safety (OFAS), Center for Food Safety and Applied Nutrition (CFSAN). OFAS is providing these draft guidances as part of its implementation of 21 CFR part 11 and the Food Additives Regulatory Management (FARM) Project.

DATES: Submit written or electronic comments concerning these draft guidances by [*insert date 60 days after date of publication in the* **Federal Register**], to ensure adequate consideration in the preparation of revised guidances, if warranted. However, you may submit written or electronic comments at any time. Submit written comments concerning the collection of information by [*insert date 60 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written comments concerning these draft guidances and the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630

Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. All comments should be identified with the corresponding docket number found in brackets in the heading of this document. Submit written requests for single copies of the draft guidances for industry entitled "Providing Regulatory Submissions to Office of Food Additive Safety in Electronic Format—General Considerations" and "Providing Regulatory Submissions to Office of Food Additive Safety in Electronic Format for Food Additive and Color Additive Petitions," to the Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the draft guidance may be sent. Alternatively, you may request a copy of the draft guidances by calling 202–418–3100, or you may fax your request to 202–418–3131. All requests should identify the draft guidances by the titles listed above. See the **SUPPLEMENTARY INFORMATION** section for electronic access to these draft guidances.

FOR FURTHER INFORMATION CONTACT: JoAnn Ziyad, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3116.

SUPPLEMENTARY INFORMATION:

I. Background

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(a)) provides that a food additive shall be deemed to be unsafe unless: (1) It and its use or intended use are in conformity with a regulation prescribing the condition(s) under which such additive may safely be used; (2) it and its use or intended use conform to the terms of a regulatory exemption for investigational use; or (3) for a food contact substance, the substance and the use of such substance are in conformity with a regulation prescribing the conditions under which such additive may be safely used or a food contact notification submitted under section 409(h) of the

act is effective. Section 409(b) of the act specifies the information that must be submitted by a petitioner in order to establish the conditions under which a food additive may be safely used.

To implement the provisions of section 409 of the act, FDA has issued regulations under part 171 (21 CFR part 171). These procedural regulations are designed to delineate and specify the information that must be submitted to meet the statutory requirements. The regulations provide a standard format for submission, which assists in the processing of the petition.

Section 721(a) of the act (21 U.S.C. 379e(a)) provides that a color additive shall be deemed to be unsafe unless: (1) The additive and its use are in conformity with a regulation listing such additive for such use, including any provision that describes the condition(s) under which the additive may safely be used and is either batch certified for such use or exempted from the certification requirements; or (2) the additive and its use conform to the terms of an exemption for investigational use issued under section 721(f) of the act. Section 721(b) of the act specifies the information that must be submitted by a petitioner in order to establish that a color additive is safe and suitable for its proposed use.

To implement the provisions of section 721 of the act, FDA has issued regulations for submission of color additive petitions under part 71 (21 CFR part 71). These procedural regulations are designed to delineate and to specify the information that must be submitted to meet the statutory requirements. The regulations provide a standard format for submission, which assists in the processing of the petition.

In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA published the final rule on Electronic Records; Electronic Signatures (21 CFR part 11). That final rule applies to all FDA program areas and to any paper records and handwritten signatures executed on paper that are required by statute or agency regulations. On January 28, 1999 (64 FR 4433), the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) announced the availability of guidance for industry on "Providing Regulatory Submission in Electronic Format—General Considerations." Prior to publication of this guidance, OFAS

participated in a number of the discussions and meetings with CDER, CBER, and other centers within the agency with respect to guidelines for electronic submissions.

FDA is now announcing the availability of two draft guidance documents for industry entitled "Providing Regulatory Submissions to Office of Food Additive Safety in Electronic Format—General Considerations" and "Providing Regulatory Submissions to Office of Food Additive Safety in Electronic Format for Food Additive and Color Additive Petitions." Attached as appendices to the latter draft guidance are Form No. 3503, entitled "Food Additive Petition Submission Application," Form No. 3504, entitled "Color Additive Petition Submission Application," and accompanying instructions for both of these forms. The draft guidance on general considerations for electronic submissions addressed in this notice is similar in many respects, though not identical, to the guidance published by CDER and CBER (64 FR 4433). However, because OFAS only proposes to accept food and color additive petitions in electronic format at this time, the only present, practical application of this draft guidance on general considerations is to food and color additive petitions. The draft guidance for the submission of food additive and color additive petitions reflects a further refinement of the guidance on general considerations with respect to food additive and color additive petitions submitted to OFAS. (See §§ 71.1 and 171.1.) Attached as appendices to the draft guidance on food and color additive petitions are Form No. 3503, entitled "Food Additive Petition Submission Application," Form No. 3504, entitled "Color Additive Petition Submission Application," and accompanying instructions for both of these forms.

OFAS intends to update guidance documents on electronic regulatory submissions regularly to reflect the evolving nature of the technology involved and the experience of those using this technology. Although the guidance for one center with respect to electronic submissions may differ from that for another center, in some cases, due to differences in procedures and computer infrastructures, OFAS will work to minimize these differences wherever possible.

The draft guidances announced in this notice are also part of OFAS's efforts under the FARM project. FDA initiated the FARM project in June 1995 as part of a comprehensive plan, in which

FDA made a commitment to Congress to provide resources to improve the efficiency and functioning of the food additive and color additive review program. In implementing the FARM project, OFAS and CFSAN have developed an electronic data management system used for the storage and retrieval of information and data necessary for the review of food additive and color additive petitions. This electronic data management system is designed to expedite the petition review process and subsequent agency safety decisions and also to help FDA perform associated activities better, such as responding to Freedom of Information Act requests and managing correspondence. The submission of food additive and color additive petitions in a consistent format will facilitate the use of the electronic data management system developed under the FARM project.

The information to be collected by way of electronically submitted food additive and color additive petitions is the same information that is currently collected in petitions submitted as paper records. FDA believes that these forms will facilitate both the preparation and review of food and color additive petitions because these forms will serve to organize information necessary to support the safety of the use of food and color additives and, therefore, to decrease the overall paperwork burden. The burden of filling out the appropriate form and preparing the electronic media is not expected to increase the reporting and paperwork burden estimates for food and color additives petitions.

II. Significance of Guidance

The two draft guidance documents represent OFAS's current thinking on the format for the data and information in an electronically submitted petition for the use of a food or color additive. These draft guidance documents do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations. These two draft guidance documents are level 1 guidances and are being distributed for comment in accordance with FDA's good guidance practices regulation (21 CFR 10115; 65 FR 56468, September 19, 2000).

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

Because OFAS proposes to collect food and color additive petitions in electronic format, in addition to a paper copy, at the present time, the following analysis contemplates only the paperwork burden stemming from the submission of food and color additive petitions in electronic format. In the event that OFAS proposes to accept other forms of regulatory submissions in electronic format, we will analyze the paperwork burden for such submissions at that time.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Providing Regulatory Submissions in Electronic Format for Food Additive and Color Additive Petitions

Section 409(a) of the act provides that a food additive shall be deemed to be unsafe unless: (1) It and its use or intended use are in conformity with a regulation prescribing the condition(s) under which such additive may safely be used; (2) it and its use or intended use conform to the terms of a regulatory exemption for investigational use; or (3) for a food contact substance, the substance and the use of such substance are in conformity with a regulation prescribing the conditions under which such additive may be safely used or a food contact notification submitted under section 409(h) of the act is effective. Individuals or companies submit food additive petitions to obtain approval of a new food additive or to amend the conditions of use permitted under an existing food additive regulation. Section 171.1 specifies the information that a petitioner must submit in order to establish that the proposed use of a food additive is safe for its proposed use. This regulation implements section 409(b)(2) of the act.

Section 721(a) of the act provides that a color additive shall be deemed to be unsafe unless: (1) The additive and its use are in conformity with a regulation listing such additive for such use, including any provision that describes the condition(s) under which the additive may safely be used and is either batch certified for such use or exempted from the certification requirements; or (2) the additive and its use conform to the terms of an exemption for investigational use issued under section 721(f) of the act. Individuals or companies submit color additive petitions to obtain approval of a new color additive or a change in the conditions of use permitted for a color additive that is already approved. Section 71.1 specifies the information that a petitioner must submit in order to establish that a color additive is safe and suitable for its proposed use.

Respondents to this collection of information are businesses engaged in the manufacture or sale of food, food ingredients, substances used in materials that come into contact with food or engaged in the manufacture or sale of foods, drugs, devices, or cosmetics containing color additives.

The agency estimates that up to 30 percent of the petitioners for both food and color additives will take advantage of the electronic submission process during the first year. By using the guidelines, including the forms that FDA is providing, the petitioner will be able to organize the petition to focus on the information needed to expedite review of the petition. Therefore, we estimate that petitioners will only need to spend approximately 1 hour completing the electronic submission application form (FDA Form 3503 or 3504, as appropriate) because they will have already organized the information needed for the submission into the appropriate categories.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section/Part/FDA Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Operating and Maintenance Costs
Food additive petitions[2]—electronic submissions						
FDA Form 3503	3	1	3	1	3	0
171.1—electronic submissions	3	1	3	4,799	14,397	0
172—electronic submissions	3	1	3	0	0	0
173—electronic submissions	3	1	3	0	0	0
175 through 178—electronic submissions	3	1	3	0	0	0
180—electronic submissions	3	1	3	0	0	0
Subtotal					14,400	0
Color additive petitions[2]—electronic submissions						
FDA Form 3504	1	1	1	1	1	0
70.25—electronic submissions	0	0	0	0	0	0
71.1 category A[3]—electronic submissions	1	1	1	608	608	2,600
71.1 category B[4]—electronic submissions	1	1	1	2,394	2,394	3,000
71.1 category C[5]—electronic submissions	0	0	0	0	0	0
Subtotal					3,003	$5,600
Total					17,403	$5,600

[1] There are no capital costs associated with this collection of information.
[2]The electronic submissions (e-submissions) contain the same petition information required for paper submissions; only the submission format will contain both electronic and paper.
[3]Category A—A color additive petition with minimal testing requirements, such as is typical for medical device color additive petitions (toxicity studies, collection of identity information, analytical information, and administrative details).
[4]Category B—An average color additive petition consisting of analytical work, 90-day feeding study, and the administrative details, which include the drafting of the regulations.
[5]Category C—A petition for a completely new food, drug, or cosmetic color.

Under parts 71 and 171, the agency requires that the petitioner submit the petitions in triplicate. The draft guidance for industry entitled ‘‘Providing Regulatory Submissions to Office of Food Additive Safety in Electronic Format for Food Additive and Color Additive Petitions’’ provides that petitioner should include one copy of the petition in electronic format (‘‘electronic copy’’) and one copy in paper format (‘‘paper copy’’). The submission of an electronic copy, however, is not

expected to significantly increase the burden of preparing the submission because it merely serves as a substitute for paper copies. Further, the agency also plans to hold consultations with the petitioners during the time of preparation to ensure that the information that the petitioners submit meets the current requirements in parts 71 and 171 and that it is in the recommended format.

The estimate of burden for electronically submitted food additive petitions is based on the number of new food additive petitions received in fiscal year (FY) 1999 and the total hours expended by petitioners to prepare the petitions. We estimate that during the first year, the electronic submission process will reduce the total time of preparation for food additive petitions by approximately 10 percent of the burden previously estimated for paper petitions (see 65 FR 64222, October 26, 2000). Although the burden varies with the type of petition submitted, an average food additive petition involves review of appropriate scientific studies, as well as the work of drafting the petition itself. The burden varies depending on the complexity of the petition, including the amount and types of data needed for scientific analysis.

The estimate of burden for electronically submitted color additive petitions is based on an average of five new color additive petitions received each year in FY 1998 and 1999. We estimate that during the first year, the electronic submission process will reduce the total time of preparation for color additive petitions by approximately 10 percent of the burden previously estimated for paper petitions (see 64 FR 51128, September 21, 1999). Although the burden varies with the type of petition submitted, an average color additive petition involves analytical work and appropriate toxicology studies, as well as the work of drafting the petition itself.

If an average of five color additive petitions (all submissions) are expected per calendar year, and only one submission per category for categories A and B is an electronic submission, the estimated annual burden for this start-up cost would be approximately $5,600. Based on the assumption that companies will use the same equipment for generating both paper and electronic records after this initial start-up cost, i.e., software and storage media for preparing both paper and electronic submissions, the burden of maintaining electronic equipment and of maintaining

electronic records should not increase the burden of preparing such petitions. In fact, the cost of shipping electronic media should be less than shipping paper copies of petitions.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on each of the two draft guidances by [*insert date 60 days after date of publication in the* **Federal Register**], to ensure adequate consideration of the comments in the preparation of revised guidances, if warranted. However, interested persons may submit written or electronic comments at any time. Two copies of any comments are to be submitted pertaining to each guidance document, as applicable, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Submit written comments concerning this collection of information to the Dockets Management Branch by [*insert date 60 days after date of publication in the* **Federal Register**]. The draft guidance documents and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain the guidances at http://www.cfsan.fda.gov/~dms/opa-toc.html.

Dated: July 19, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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